K110834

GE Healthcare

AW VolumeShare 5 with AngioViz Option
510(k) Premarket Notification

APR 26 2011

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	March 24th, 2011
Submitter:	GE Medical Systems SCS 283, rue de la Minière BP34 78533 Buc Cedex - FRANCE
Primary Contact Person:	Helen Peng, RAC Regulatory Affairs Leader GE Healthcare TEL: 262-548-5091 FAX: 262-548-3844
Secondary Contact Person:	Stephen G. Slavens, RAC Regulatory Affairs Director GE Healthcare TEL: (262) 548-4992 FAX: (262) 548-3884
Device: Trade Name:	AW VolumeShare 5 with AngioViz Option
Common/Usual Name:	AW VolumeShare 5 with AngioViz Option
Classification Name:	21CFR 892.2050 Picture archiving and communications system
Product Code:	LLZ
Predicate Devices:	**Advantage Workstation 4.3** (K052995)
Device Description:	The AW VolumeShare 5 is a stand-alone workstation with its own image database residing on its dedicated computer. The AW VolumeShare 5 workstation supports functions for image display, manipulation, and selective recording (either on film or on disk). The AW VolumeShare 5 is intended to be used to create and review diagnostic evidence related to radiology procedures by trained and licensed physicians and/or qualified clinical/medical personnel. The device is not intended for diagnosis of mammography images AW VolumeShare 5 workstation, like its predicate Advantage Workstation 4.3, provides a platform for a variety of other GE software medical devices to operate , all of which are cleared by FDA in their own names. AngioViz is an option offered on AW Volume Share 5. It is an integrated post processing image analysis software dedicated to the application of vascular imaging on body vessels. **AngioViz** is an application which produces from a DSA series

parametric images representing maximum opacification, time to peak and combinations of those, to enable the user to more easily visualize characteristics related to vascular flow.

The AngioViz application can be used to process DSA image data from any location in the human body for which DSA imaging is used.

Intended Use: **AW VolumeShare 5** is a review workstation, which allows easy selection, review, processing and filming of multi-modality DICOM images from a variety of diagnostic imaging systems. When interpreted by a trained physician, filmed or displayed images on the AW monitor may be used as a basis of diagnosis, except in the case of mammography images.

Technology: AW VolumeShare 5 with AngioViz option employs the same technology as that of its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

AW VolumeShare 5 with AngioViz complies with voluntary standards as detailed in Section 9, 11 and 16 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (Verification)
- Safety testing (Verification)
- Final acceptance testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, AW VolumeShare 5 with AngioViz, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the AW VolumeShare 5 with AngioViz Software application to be as safe, as effective, and its performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Helen Peng, RAC
Regulatory Affairs Leader
GE Healthcare
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APR 2 6 2011

Re: K110834
Trade/Device Name: AW VolumeShare 5 with AngioViz Option
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 24, 2011
Received: March 25, 2011

Dear Ms. Peng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: **AW VolumeShare 5 with AngioViz Option**

Indications for Use:

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AngioViz is an application which produces from a DSA series parametric images representing maximum opacification, time to peak and combinations of those, to enable the user to more easily visualize characteristics related to vascular flow.

The AngioViz application can be used to process DSA image data from any location in the human body for which DSA imaging is used.

Prescription Use_X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K110834